

Docket No. PHUS-7

AMENDMENTS TO THE CLAIMS

- 1) (Previously amended) A multi-layered osmotic device for the controlled delivery of one or more active agents to one or more environments of use wherein the osmotic device comprises:
- a) a compressed core comprising a first active agent and an osmotic agent for controlled and continuous release of the first active agent;
  - b) a semipermeable membrane surrounding the core and having a preformed passageway therein, said semipermeable membrane being permeable to a fluid in the environment of use and substantially impermeable to the first active agent;
  - c) an inert, completely erodible and/or water soluble polymer coat comprising poly(vinylpyrrolidone)-(vinyl acetate) copolymer partially or substantially completely surrounding the semipermeable membrane and plugging the passageway in the wall; and
  - d) an external coat comprising a second active agent for immediate release of the second active agent, wherein the first active agent is released from the core after the polymer coat has partially or completely dissolved or eroded, and the first and second active agents are released into the same or different environments of use to provide a controlled delivery of the one or more active agents.
- 2) (original) An osmotic device according to claim 1 wherein the compressed core further comprises poly(vinylpyrrolidone).
- 3) (original) An osmotic device according to claim 1 wherein the semipermeable membrane consists essentially of cellulose acetate and poly(ethylene glycol).
- 4) (original) An osmotic device according to claim 1 wherein the external coat comprises poly(vinylpyrrolidone) and poly(ethylene glycol).
- 5) (original) An osmotic device according to claim 1 wherein the second active agent in the external coat comprises a therapeutic agent.
- 6) (original) An osmotic device according to claim 1 wherein the first active agent in the core comprises a therapeutic agent.
- 7) (original) An osmotic device according to claim 1 wherein the second active agent in the external coat comprises a therapeutic agent and the first active agent in the core comprises a therapeutic agent.
- 8) (original) An osmotic device according to claim 7 wherein the first and second active

Docket No. PHUS-7

agents are the same.

- 9) (original) An osmotic device according to claim 8 wherein the first and second active agents are theophylline.
- 10) (original) An osmotic device according to claim 1 wherein the second active agent in the external coat comprises a therapeutic agent and the first active agent in the core comprises a different therapeutic agent.
- 11) (original) An osmotic device according to claim 10 wherein the first active agent is pseudoephedrine and the second active agent is loratadine.
- 12) (original) An osmotic device according to claim 10 wherein the first active agent is ranitidine and the second active agent is a combination of ranitidine and cisapride.
- 13) (original) An osmotic device according to claim 10 wherein the first active agent is pseudoephedrine and the second active agent is astemizole.
- 14) (original) An osmotic device according to claim 10 wherein the first active agent is diltiazem and the second active agent is enalapril.
- 15) (original) An osmotic device according to claim 1, wherein the one or more environments of use comprises a first environment of use and a different second environment of use.
- 16) (original) An osmotic device according to claim 15, wherein the first environment of use is the gastric region and the second environment of use is farther down the gastrointestinal tract of a mammal.
- 17) (original) An osmotic device according to claim 1, wherein the first and second active agents are released into the same environment of use.
- 18) (original) An osmotic device according to claim 1, wherein the controlled delivery of one or more active agents includes one or more of pH-dependent, pH-independent, diffusion controlled, dissolution controlled, pseudo-zero order, zero-order, pseudo-first order, first-order, second-order, rapid, slow, delayed, timed, and sustained delivery.
- 19) (original) An osmotic device according to claim 1, wherein at least a portion of the polymer coat dissolves or erodes in fluid present in an environment of use after the external coat has at least partially dissolved in an environment of use.
- 20) (original) An osmotic device according to claim 1, wherein the polymer coat is one or more of soluble in the same environment of use in which the external coat is soluble, and soluble in the same environment of use in which the core is soluble.

Docket No. PHUS-7

- 21) (original) An osmotic device according to claim 1, wherein the semipermeable membrane comprises a plasticizer and one or more of a cellulose ether, cellulose ester and cellulose-ester-ether.
- 22) (original) An osmotic device according to claim 1, wherein the external coat further comprises poly(vinylpyrrolidone).
- 23) (original) An osmotic device according to claim 1, wherein the polymer coat further comprises one or more of talc and poly(ethylene glycol).
- 24) (Currently amended) A multi-layered osmotic device for the controlled delivery of one or more active agents to one or more environments of use wherein the osmotic device comprises:
- a) a compressed core comprising a first active agent and an osmotic agent for controlled and continuous release of the first active agent;
  - b) a semipermeable membrane surrounding the core and having a preformed passageway therein, said semipermeable membrane being permeable to a fluid in the environment of use and substantially impermeable to the first active agent;
  - c) an inert, completely erodible and/or water soluble polymer coat partially or completely surrounding the semipermeable membrane and plugging the passageway in the wall; and
  - d) an external coat comprising a second active agent for immediate release of the second active agent, ~~wherein the first active agent is released from the core after the polymer coat has partially or completely dissolved or eroded, and the first and second active agents are released into the same or different environments of use to provide a controlled delivery of the one or more active agents wherein the osmotic device operates as follows in the one or more environments of use: the external coat partially or completely dissolves, erodes, swells and/or detaches from the osmotic device thereby releasing the second active agent and exposing the polymer coat; at least a portion of the polymer coat then dissolves and/or erodes thereby exposing the semipermeable membrane and the preformed passageway; the first active agent is then released from the core, such that the first and second active agents are released into the same or different environments of use to provide a controlled delivery of the one or more active agents.~~

Docket No. PHUS-7

25) (Currently amended) A multi-layered osmotic device for the controlled delivery of one or more active agents to one or more environments of use wherein the osmotic device comprises:

- a) a compressed core comprising a first active agent and at least one osmotic agent for controlled and continuous release of the first active agent;
- b) a semipermeable membrane surrounding the core and having at least one preformed passageway therein;
- c) an inert, completely erodible and/or water soluble polymer coat partially or completely surrounding the semipermeable membrane and plugging the passageway in the wall; and
- d) an external coat comprising a second active agent for immediate release of the second active agent, wherein the first active agent is released from the core after the polymer coat has partially or completely dissolved or eroded, and the first and second active agents are released into the same or different environments of use wherein the osmotic device operates as follows in the one or more environments of use: the external coat partially or completely dissolves, erodes, swells and/or detaches from the osmotic device thereby releasing the second active agent and exposing the polymer coat; at least a portion of the polymer coat then dissolves and/or erodes thereby exposing the semipermeable membrane and the preformed passageway; the first active agent is then released from the core, such that the first and second active agents are released into the same or different environments of use to provide a controlled delivery of the one or more active agents.

26) (Currently amended) A multi-layered osmotic device for the controlled delivery of one or more active agents to one or more environments of use wherein the osmotic device comprises:

- a) a compressed core comprising a first active agent and at least one osmotic agent for controlled and continuous release of the first active agent;
- b) a semipermeable membrane surrounding the core and having at least one preformed passageway therein;
- c) an inert, completely erodible and/or water soluble polymer coat partially or completely surrounding the semipermeable membrane and plugging the at least one

Docket No. PHUS-7

preformed passageway in the wall; and

- d) an external coat comprising a second active agent for release of the second active agent, wherein the first active agent is released from the core after the polymer coat has partially or completely dissolved or eroded, and the first and second active agents are released into the same or different environments of use wherein the osmotic device operates as follows in the one or more environments of use: the external coat partially or completely dissolves, erodes, swells and/or detaches from the osmotic device thereby releasing the second active agent and exposing the polymer coat; at least a portion of the polymer coat then dissolves and/or erodes thereby exposing the semipermeable membrane and the preformed passageway; the first active agent is then released from the core, such that the first and second active agents are released into the same or different environments of use to provide a controlled delivery of the one or more active agents.

27) (Currently amended) A multi-layered osmotic device for the controlled delivery of one or more active agents to one or more environments of use wherein the osmotic device comprises:

- a) a compressed core comprising a first active agent and at least one osmotic agent for controlled and continuous release of the first active agent;
- b) a semipermeable membrane surrounding the core and having at least one preformed passageway therein;
- c) an inert, completely erodible and/or water soluble polymer coat partially or completely surrounding the semipermeable membrane and plugging the at least one preformed passageway in the wall; and
- d) an external coat comprising a second active agent for immediate, rapid, delayed, slow, sustained, pseudo-first order, pseudo-zero order, timed, controlled or combination thereof release of the second active agent, wherein the first active agent is released from the core after the polymer coat has partially or completely dissolved or eroded, and the first and second active agents are released into the same or different environments of use wherein the osmotic device operates as follows in the one or more environments of use: the external coat partially or completely dissolves, erodes, swells and/or detaches from the osmotic device thereby releasing the second active

Docket No. PHUS-7

agent and exposing the polymer coat; at least a portion of the polymer coat then dissolves and/or erodes thereby exposing the semipermeable membrane and the preformed passageway; the first active agent is then released from the core, such that the first and second active agents are released into the same or different environments of use to provide a controlled delivery of the one or more active agents.

- 28) (Previously added) The multi-layered osmotic device of claim 24, 25, 26 or 27, wherein the first and second active agents each comprise a therapeutic agent.
- 29) (Previously added) The multi-layered osmotic device of claim 24, 25, 26 or 27, wherein the first and second active agents are the same.
- 30) (Previously added) The multi-layered osmotic device of claim 24, 25, 26 or 27, wherein the first and second active agents are different.
- 31) (Previously added) The multi-layered osmotic device of claim 24, 25, 26 or 27, wherein the first and second active agents are released into different environments of use.
- 32) (Previously added) The multi-layered osmotic device of claim 24, 25, 26 or 27, wherein the first and second active agents are released into the same environment of use.
- 33) (Previously added) The multi-layered osmotic device of claim 24, 25, 26 or 27, wherein the controlled delivery of one or more active agents includes one or more of pH-dependent, pH-independent, diffusion controlled, dissolution controlled, pseudo-zero order, zero-order, pseudo-first order, first-order, second-order, rapid, slow, delayed, timed, and sustained delivery.
- 34) (Previously added) The multi-layered osmotic device of claim 1, 24, 25, 26 or 27, wherein the first and second active agents are independently selected at each occurrence from the group consisting of antibacterial, antihistamine, decongestant, anti-inflammatory, antiparasitic, antiviral, local anesthetic, antifungal, amoebicidal, trichomonocidal, analgesic, antiarthritic, antiasthmatic, anticoagulant, anticonvulsant, antidepressant, antidiabetic, antineoplastic, antipsychotic, neuroleptic, antihypertensive, muscle relaxant, depressant, hypnotic, sedative, psychic energizer, tranquilizer, antiparkinson, muscle contractant, anti-microbial, antimalarial, hormonal, contraceptive, sympathomimetic, diuretic, hypoglycemic, ophthalmic, electrolyte, diagnostic and cardiovascular agent.
- 35) (Previously added) The multi-layered osmotic device of claim 1, 24, 25, 26 or 27, wherein the first and second active agents are independently selected at each occurrence

Docket No. PHUS-7

from the group consisting of pesticide, herbicide, insecticide, antioxidant, plant growth instigator, sterilization agent, catalyst, chemical reagent, food product, nutrient, cosmetic, vitamin, sterility inhibitor, fertility instigator, microorganism, flavoring agent, sweetener, and cleansing agent.

- 36) (Previously amended) A multi-layered osmotic device for the controlled delivery of one or more active agents to one or more environments of use wherein the osmotic device comprises:
- a) a compressed core comprising a first active agent and at least one osmotic agent for controlled and continuous release of the first active agent;
  - b) a semipermeable membrane surrounding the core and having at least one preformed passageway therein;
  - c) an inert, completely erodible and/or water soluble polymer coat partially or completely surrounding the semipermeable membrane and plugging the passageway in the wall; and
  - d) an external coat comprising a second active agent for immediate release of the second active agent, wherein the first active agent is released from the core after the polymer coat has partially or completely dissolved or eroded, and the first and second active agents are released into the same or different environments of use, wherein the inert, completely erodible and/or water soluble polymer coat comprises poly(vinylpyrrolidone)-(vinyl acetate) copolymer.
- 37) (Previously amended) The multi-layered osmotic device of claim 36, wherein the inert, completely erodible and/or water soluble polymer coat further comprises a second polymer.
- 38) (Previously added) The multi-layered osmotic device of claim 36, wherein the semipermeable membrane comprises a plasticizer and one or more of a cellulose ether, cellulose ester and cellulose-ester-ether.
- 39) (Previously added) The multi-layered osmotic device of claim 38, wherein the polymer coat further comprises one or more of talc and poly(ethylene glycol).
- 40) (Previously amended) The multi-layered osmotic device of claim 1, 24, 25, 26 or 27, wherein the inert, completely erodible and/or water soluble polymer coat comprises at least two different polymers.

Docket No. PHUS-7,

- 41) (Previously added) The multi-layered osmotic device of claim 1, 24, 25, 26 or 27, wherein the delivery of the first active agent is delayed with respect to delivery of the second active agent.
- 42) (Previously added) The multi-layered osmotic device of claim 1, 24, 25, 26 or 27, wherein the first active agent is ranitidine and the second active agent is a combination of ranitidine and cisapride.
- 43) (Previously added) The multi-layered osmotic device of claim 1, 24, 25, 26 or 27, wherein the first active agent is pseudoephedrine and the second active agent is astemizole.
- 44) (Previously added) The multi-layered osmotic device of claim 1, 24, 25, 26 or 27, wherein the first active agent is pseudoephedrine and the second active agent is loratadine.
- 45) (Previously added) The multi-layered osmotic device of claim 1, 24, 25, 26 or 27, wherein the first active agent is diltiazem and the second active agent is enalapril.
- 46) (Previously added) The multi-layered osmotic device of claim 1, 24, 25, 26 or 27, wherein the first and second active agents are theophylline.
- 47) (Previously added) The multi-layered osmotic device of claim 1, 24, 25, 26 or 27, wherein the first active agent is a decongestant and the second active agent is an antihistamine.
- 48) (Previously added) The multi-layered osmotic device of claim 1, 24, 25, 26 or 27, wherein the first active agent is a first antihypertensive agent and the second active agent is a different second antihypertensive agent.
- 49) (Previously added) The multi-layered osmotic device of claim 1, 24, 25, 26 or 27, wherein the first active agent is a gastric acid inhibitor and the second active agent is a gastrointestinal emptying adjunct agent.
- 50) (Previously added) A multi-layered osmotic device for the controlled delivery of one or more active agents to one or more environments of use wherein the osmotic device comprises:
- a) a compressed core comprising a first active agent and at least one osmotic agent for controlled and continuous release of the first active agent;
  - b) a semipermeable membrane surrounding the core and having at least one preformed



Docket No. PHUS-7

passageway therein;

- c) an inert, completely erodible and/or water soluble polymer coat partially or completely surrounding the semipermeable membrane and plugging the at least one preformed passageway in the wall, wherein the inert, completely erodible and/or water soluble polymer coat comprises poly(vinylpyrrolidone)-(vinyl acetate) copolymer; and
  - d) an external coat comprising a second active agent for release of the second active agent, wherein the first active agent is released from the core after the polymer coat has partially or completely dissolved or eroded, and the first and second active agents are released into the same or different environments of use.
- 51) (Previously added) The multi-layered osmotic device of claim 50, wherein the inert, completely erodible and/or water soluble polymer coat further comprises a second polymer.
- 52) (Previously added) The multi-layered osmotic device of claim 50, wherein the semipermeable membrane comprises a plasticizer and one or more of a cellulose ether, cellulose ester and cellulose-ester-ether.
- 53) (Previously added) A multi-layered osmotic device for the controlled delivery of one or more active agents to one or more environments of use wherein the osmotic device comprises:
- a) a compressed core comprising a first active agent and at least one osmotic agent for controlled and continuous release of the first active agent;
  - b) a semipermeable membrane surrounding the core and having at least one preformed passageway therein;
  - c) an inert, completely erodible and/or water soluble polymer coat partially or completely surrounding the semipermeable membrane and plugging the at least one preformed passageway in the wall, wherein the inert, completely erodible and/or water soluble polymer coat comprises poly(vinylpyrrolidone)-(vinyl acetate) copolymer; and
  - d) an external coat comprising a second active agent for immediate, rapid, delayed, slow, sustained, pseudo-first order, pseudo-zero order, timed, controlled or combination thereof release of the second active agent, wherein the first active agent is released

Docket No. PHUS-7

from the core after the polymer coat has partially or completely dissolved or eroded, and the first and second active agents are released into the same or different environments of use.

- 54) (Previously added) The multi-layered osmotic device of claim 53, wherein the inert, completely erodible and/or water soluble polymer coat further comprises a second polymer.
- 55) (Previously added) The multi-layered osmotic device of claim 53, wherein the semipermeable membrane comprises a plasticizer and one or more of a cellulose ether, cellulose ester and cellulose-ester-ether.